

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EXELA PHARMA SCIENCES, LLC,

Plaintiff,

v.

SANDOZ, INC.

Defendant.

C.A. No. 1:20-cv-645-MN

Public Version Filed on August 7, 2020

STIPULATION AND [PROPOSED] ORDER OF DISMISSAL

WHEREAS Plaintiff Exela Pharma Sciences, LLC (“Exela”) filed the above-captioned patent litigation against Defendant Sandoz, Inc. (“Sandoz”) on May 14, 2020;

WHEREAS Exela is the owner of U.S. Patent Nos. 10,478,453 (the “’453 patent”); 10,583,155 (the “’155 patent”), and 10,653,719 (the “’719 patent”);

WHEREAS Exela is the holder of NDA No. 210660 for L-cysteine hydrochloride injection, which it sells under the trade name Elcys®;

WHEREAS the ’453, ’155, and ’719 patents are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”) for NDA No. 210660;

WHEREAS by letter dated April 2, 2020, and received by Exela on or about April 3, 2020, Sandoz provided notice pursuant to 21 U.S.C. § 355(j)(2)(B) (“the Paragraph IV Letter”) of Paragraph IV certifications of alleged invalidity and/or non-infringement of the ’453 and ’155 patents with respect to ANDA No. 209994 for L-cysteine hydrochloride injection USP, 500 mg/10mL (50 mg/mL);

WHEREAS Exela commenced the above-captioned action before the expiration of 45 days after the date on which Exela received the Paragraph IV Letter;

WHEREAS as a result of the filing of the above-captioned litigation, final approval by FDA of Sandoz's ANDA was stayed for thirty months pursuant to 21 U.S.C. § 355(j)(5)(B)(iii);

WHEREAS on July 27, 2020, before Sandoz answered or otherwise responded to the Complaint, Sandoz notified Exela that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

NOW THEREFORE, it is hereby stipulated and agreed, by and between Exela and Sandoz, through their undersigned counsel and subject to approval of the Court, that:

1. Plaintiff's claims are hereby dismissed without prejudice.
2. Each party shall bear its own costs, expenses, and taxes in connection with this action.
3. The U.S. District Court for the District of Delaware retains jurisdiction to resolve any disputes arising under this stipulation of dismissal.

August 7, 2020

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SO ORDERED, this 7th day of August, 2020.

United States District Court Judge